

CLAIMS:

1. Apparatus for performing cardiac ablation in a mammalian subject comprising:

(a) an insertable structure, said insertable structure including:

(i) a catheter having proximal and distal ends; and

(ii) an ablation device mounted to the catheter adjacent the distal end thereof, said ablation device being adapted for placement within a chamber of the heart of a mammalian subject and adapted to ablate a region of the cardiac structure bounding such chamber when the ablation device is in an operative configuration,

said insertable structure defining an outlet port open to a distal side of the ablation device and a continuous passageway extending from adjacent said proximal end of said catheter to said outlet port; and

(b) a source of a contrast medium adapted for connection to said passageway and operative to pass the contrast medium through the passageway and into the subject through the outlet port while the ablation device is in said operative configuration.

2. Apparatus as claimed in claim 1 wherein said catheter has a lumen, said lumen forms at least a part of said continuous passageway and wherein said source of contrast medium is adapted for connection to said lumen adjacent the proximal end of the catheter.

3. Apparatus as claimed in claim 1 wherein said insertable structure further includes a hollow stylet, said stylet being adapted to extend through said catheter and said ablation device while said ablation device is in said operative condition, said source of contrast medium being adapted for connection to said stylet.

4. Apparatus as claimed in claim 1 wherein said ablation device includes an expansible structure having a collapsed, inoperative state and an expanded state constituting said operative condition.

5. Apparatus as claimed in claim 4 wherein said expansible structure includes at least one balloon.

6. Apparatus as claimed in claim 1 wherein said ablation device includes an ultrasonic emitter and a reflector for directing emitted ultrasonic waves from said emitter generally in the distal direction.

7. A method of performing cardiac ablation comprising:

(a) providing an ablation device in a chamber of the heart of a mammalian subject such that the device is in an operative configuration with a distal side of the device facing toward a region of the cardiac structure to be ablated; and

(b) while the ablation device is in said operative configuration, injecting a contrast medium into said chamber on the distal side of said ablation device.

8. A method as claimed in claim 7 further comprising obtaining one or more images depicting said contrast medium in at least a portion of the cardiac structure.

9. A method as claimed in claim 8 wherein said contrast medium is an x-ray contrast medium and said step of obtaining said images is performed by x-ray imaging.

10. A method as claimed in claim 8 wherein said chamber of the heart is the left atrium and wherein said steps of injecting contrast medium and obtaining images are performed so that said images show contrast medium in the atrium and in at least one pulmonary vein.

11. Apparatus for performing cardiac ablation in the heart of a mammalian subject comprising:

(a) a catheter;

(b) an ultrasonic ablation device having a forward-to-rearward axis, said ultrasonic ablation device being adapted to emit ultrasonic waves so that the emitted ultrasonic waves are directed into at least a portion of a loop-like region surrounding said forward to rearward axis, said ablation device being mounted to said catheter; and

(c) a steering system adapted to selectively vary the disposition of the forward-to-rearward axis of the ultrasonic ablation device relative to the heart of the subject while the ultrasonic ablation device is disposed in a chamber of the heart of the subject.

12. Apparatus as claimed in claim 11 wherein said ultrasonic ablation device includes an expansible structure having a collapsed, inoperative state and an expanded, state, said steering system being operative to selectively vary said disposition while said expansible structure is in said expanded state.

13. Apparatus as claimed in claim 12 wherein said expansible structure includes at least one balloon and said steering system is operative to selectively vary said disposition while said at least one balloon is in an inflated condition.

14. Apparatus as claimed in claim 12 wherein said expansible structure includes an internal reinforcing structure having a forward end linked to said expansible structure adjacent a forward end of the expansible structure and having a proximal end linked to the expansible structure adjacent a rearward end thereof, said ends of said reinforcing structure being movable relative to one another when said expansible structure is in said collapsed condition, said ends of said reinforcing structure being constrained against movement relative to one another when said expansible structure is in said expanded condition.

15. Apparatus as claimed in claim 14 wherein said steering system includes at least one pull wire mechanically connected to said reinforcing structure adjacent the proximal end thereof.

16. Apparatus as claimed in claim 11 wherein said steering system is operative to move the balloon between a normal disposition in which said forward-to-rearward axis lies approximately perpendicular to a wall of the heart and a canted disposition in which said forward-to-rearward axis lies at a substantially non-perpendicular angle to such wall of the heart so that only a minor portion of said loop-like region is disposed within such wall.

17. Apparatus as claimed in claim 16 wherein said ablation device is operative to direct the ultrasonic waves generally in a direction of propagation into said region and to focus the ultrasonic waves so that the ultrasonic waves have energy density which increases in said direction of propagation from said device to said region and decreases in said direction of propagation beyond said region.

18. Apparatus as claimed in claim 16 wherein said ablation device is operative to direct said ultrasonic waves in a direction of propagation having a forward component.

19. Apparatus as claimed in claim 11 wherein said steering system is operative to selectively vary the disposition of said ultrasonic ablation device independently of engagement between any element of the apparatus distal to said ultrasonic ablation device and the heart.

20. Apparatus as claimed in claim 11 wherein said catheter has proximal and distal ends and a bendable section proximal to the ablation device, said steering system being operative to selectively bend the bendable section of the catheter.

21. Apparatus as claimed in claim 11 further comprising a guide element adapted to engage a portion of the heart or

vascular structure adjacent the heart, said steering system being operative to vary the disposition of the ultrasonic ablation device relative to the guide element.

22. Apparatus as claimed in claim 21 wherein said guide element is disposed distal to the ultrasonic ablation device.

23. Apparatus as claimed in claim 11 wherein said steering system includes at least one inflatable structure mechanically connected to said ultrasonic ablation device or to said catheter, said at least one inflatable structure being arranged such that inflation or deflation of said at least one inflatable structure will alter the disposition of the ultrasonic ablation device, and one or more inflation lumens connected to said inflatable structures so that said at least one inflatable structures can be selectively inflated and deflated.

24. Apparatus as claimed in claim 23 wherein at least one said inflatable structure is adapted to engage the wall of the heart.

25. Apparatus as claimed in claim 24 wherein said at least one inflatable structure includes a plurality of inflatable structures disposed around the forward-to-rearward axis of the ultrasonic ablation device.

26. Apparatus as claimed in claim 23 wherein at least one said inflatable structure extends along said bendable region of the catheter the so that inflation or deflation of such structure tends to change the curvature of such region.

27. Apparatus as claimed in claim 23 wherein said ultrasonic ablation device includes a structural balloon and at least one reflector balloon abutting said structural balloon, and wherein at least one said inflatable structure communicates with at least one said reflector balloon.

28. Apparatus as claimed in claim 27 wherein said ultrasonic ablation device includes a plurality of reflector balloons disposed around said forward-to-rearward axis and

said at least one inflatable structure includes parts of said plural reflector balloons.

29. A method of cardiac ablation in a mammalian subject comprising the steps of:

(a) advancing apparatus including a catheter bearing an ultrasonic ablation device into the subject until the ultrasonic ablation device is within a chamber of the heart;

(b) positioning the ultrasonic ablation device in a first disposition within the chamber by selectively varying the disposition of the forward-to-rearward axis of the ultrasonic ablation device relative to the catheter ;

(c) while the ultrasonic ablation device is in said first disposition, ablating the heart wall to form a first lesion by actuating the ultrasonic ablation device to direct ultrasonic waves into at least a portion of a loop-like region surrounding a forward to rearward axis of the device; and then

(d) removing the ultrasonic ablation device from the subject.

30. A method as claimed in claim 29 further comprising the steps of

(e) repositioning the ultrasonic ablation device from said first disposition to a second disposition within the chamber by further selectively varying the disposition of said axis relative to the catheter; and

(f) while the ultrasonic ablation device is in said second disposition, ablating the heart wall to form a second lesion by actuating said ultrasonic ablation device to direct ultrasonic waves into said loop-like region, said steps (e) and (f) being performed prior to said step (d), while the ultrasonic ablation device remains within said chamber.

31. A method as claimed in claim 30 wherein at least one of said dispositions is a normal disposition in which said forward-to-rearward axis lies approximately perpendicular to a

wall of the heart with at least a major portion of said loop-like region disposed within or in close proximity to the wall of the heart, and at least one of said ablating steps is performed while said ablating device is in said normal disposition so form a lesion in the shape of at least a major portion of a loop.

32. A method as claimed in claim 31 wherein at least one of said dispositions is a canted disposition in which said forward-to-rearward axis lies at a substantially non-perpendicular angle to a wall of the heart so that only a minor portion of said loop-like region is disposed within or in close proximity to a wall of the heart, and at least one of said ablating steps is performed while said ablating device is in said canted disposition so form a lesion in a generally linear shape.

33. A method as claimed in claim 32 wherein, during both of said ablating steps, said ablation device directs said ultrasonic waves into the entirety of said loop-like region.

34. A method as claimed in claim 33 wherein, during each said ablation step, said ablation device focuses said ultrasonic waves into said loop-like region so that said ultrasonic waves have an energy density which increases in a direction of propagation from said device to said region and decreases in said direction of propagation beyond said region.

35. A method as claimed in claim 34 wherein said direction of propagation has a component in a forward direction parallel to said axis.

36. A method as claimed in claim 32 wherein said chamber is the left atrium and said positioning step is performed so that at least a portion of said loop-like ablation region lies in a portion of the heart wall defining or surrounding the ostium or ostia of one or more pulmonary veins.

37. A method as claimed in claim 32 further comprising imaging at least a portion of the chamber while the ablation

apparatus is in the chamber and conducting said positioning step based at least in part on said imaging.

38. A method as claimed in claim 29 wherein said positioning step is performed independently of mechanical engagement between an element of the apparatus distal to the ultrasonic ablation device and the anatomy.

39. A method as claimed in claim 29 said chamber is the left atrium and said positioning step is performed independently of any mechanical engagement the apparatus and a pulmonary vein or pulmonary vein ostium.

40. Apparatus comprising:

(a) an ultrasonic emitter assembly having proximal and distal ends, said emitter including:

(i) a tubular piezoelectric element having proximal and distal ends; and

(ii) a inside tube extending within said tubular piezoelectric element so that said inside tube and said piezoelectric element cooperatively define an annular passageway extending between said proximal and distal ends of the piezoelectric element, said tube defining a tube bore;

(b) a balloon surrounding said emitter, said balloon having an interior space, said annular passageway communicating with the interior of said balloon adjacent the distal end of said emitter assembly;

(c) a catheter having proximal and distal ends, said catheter having a principal lumen and first and second additional lumens;

(d) said principal lumen communicating with said tube bore, said first additional lumen communicating with the proximal end of said annular passageway and said second additional lumen communicating with the interior of said balloon adjacent the proximal end of said emitter assembly.



41. Apparatus as claimed in claim 40 wherein said emitter assembly includes a proximal mounting structure disposed at least partially between the distal end of the catheter and the proximal end of the tubular piezoelectric element, said proximal mounting structure at least partially defining a port communicating with the interior of said balloon, a central bore connecting said tube bore with said principal lumen of said catheter, a first side channel connecting said first additional lumen of said catheter with said annular passageway and a second side channel connecting said second additional lumen of said catheter with said port so that the second additional lumen communicates with the interior of the balloon through said port.

42. Apparatus as claimed in claim 41 wherein said emitter assembly further includes a distal-end structure mounted to the distal end of said tubular piezoelectric element.

43. Apparatus as claimed in claim 42 wherein said distal-end structure at least partially defines an opening, said annular passageway communicating with the interior of said balloon through said opening.

44. Apparatus as claimed in claim 41 wherein said proximal mounting structure and said distal mounting structure are at least partially electrically conductive, the apparatus further and electrical conductors extending within said catheter, one of said conductors being electrically connected to said proximal mounting structure, another one of said conductors being electrically connected to said distal mounting structure, said tubular piezoelectric element having an inside surface and an outside surface, one of said end structures being connected to said inside surface, the other one of said end structures being connected to said outside surface.

45. Apparatus as claimed in claim 44 wherein at least a portion of said tube is electrically conductive, the apparatus further comprising electrical insulation disposed between said tube and said proximal mounting structure, one of said electrical conductors being electrically connected to said distal mounting structure by way of said tube.

46. Apparatus as claimed in claim 41 wherein said balloon has a distal end distal to said emitter assembly and an outlet port opening communicating with the exterior of the balloon adjacent the distal end thereof and an extensible element defining a passage connecting said outlet port to said bore of said inside tube so that said extensible element, said inside tube and said principal lumen cooperatively constitute a continuous passageway.

47. Apparatus as claimed in claim 46 wherein said extensible element includes a distensible tube having a proximal end attached to said emitter assembly and having a distal end attached to said balloon adjacent the distal end thereof.

48. Apparatus as claimed in claim 46 wherein said extensible element includes a distal reinforcing tube connected to said balloon adjacent the distal end thereof and a proximal reinforcing tube connected to said emitter assembly, said reinforcing tubes being telescopically engaged with one another.

49. Apparatus as claimed in claim 48 wherein said emitter assembly includes a distal end element, said distal reinforcing tube engaging said distal end element when said balloon is in an inflated condition, said distal reinforcing tube being disengaged from said distal end element but remaining telescopically engaged with said proximal reinforcing tube when said balloon is in a deflated condition.

50. Apparatus comprising:

- (a) a catheter having proximal and distal ends;

(b) an expansible structure mounted to said catheter adjacent the distal end thereof, said expansible structure having proximal and distal ends, an expanded condition and a collapsed condition, said proximal and distal ends being closer to one another in said expanded condition than in said collapsed condition;

(c) a reinforcing structure including a plurality of engagement elements disposed at least partially within said expansible structure, a first one of said engagement elements being connected to the distal end of the expansible structure, a second one of said engagement elements being connected to the distal end of said expansible structure, said engagement elements being engaged with one another when said expansible structure is in said expanded condition and disengaged from one another when said expansible structure is in said collapsed condition so that said reinforcing structure is more flexible when said expansible structure is in said collapsed condition than when said expansible structure is in said expanded condition, said engagement elements having interlocking features which prevent complete separation of said engagement elements from one another.

51. Apparatus as claimed in claim 50 wherein said expansible structure includes a balloon, said expanded condition is an inflated condition of the balloon, and said collapsed condition is a deflated condition of the balloon.

52. Apparatus as claimed in claim 50 further comprising a pull wire extending between the proximal and distal ends of the catheter, said pull wire being attached to said second engagement element.

53. Apparatus as claimed in claim 50 wherein one of said engagement elements is telescopically received in another one of said engagement elements.

54. Ultrasonic ablation apparatus for ablating a region of the cardiac structure adjacent an ostium of a blood vessel extending to or from the heart comprising:

- (a) a catheter having proximal and distal ends;
- (b) an ultrasonic ablation device mounted to said catheter adjacent the distal end thereof, said ultrasonic ablation device said ablation device being adapted for positioning in a blood vessel and defining a forward-to-rearward axis extending generally coaxial with the blood vessel with the rearward direction being the direction toward the heart, said ultrasonic ablation device being adapted to direct ultrasonic waves from said emitter in a rearward direction toward the heart onto at least a portion of a ring-like region of the cardiac structure encircling said forward to rearward axis rearwardly of the device.

55. A method of cardiac ablation comprising the steps of:

- (a) positioning an ablation device within a blood vessel extending to or from the heart so that a forward-to-rearward axis of the ablation device is generally coaxial with the blood vessel; and
- (b) directing ultrasonic waves from said ablation device generally rearwardly and outwardly from the axis so that the ultrasonic waves are directed onto at least a portion of a ring-like region encircling the axis rearwardly of the device.

56. A method as claimed in claim 57 wherein said blood vessel is a pulmonary vein and said ring-like region is disposed in the ostium of the pulmonary vein or in the cardiac wall encircling the ostium.

57. Apparatus for ablating the cardiac wall surrounding one or more pulmonary veins comprising an ultrasonic emitter arranged to emit ultrasonic waves directed outwardly from a forward-to-rearward axis and an ultrasonic reflector at least

partially surrounding said axis and adapted to focus ultrasonic waves onto at least a portion of a ring-like region having a diameter between 28 and 38 mm.

58. Apparatus for ablating the cardiac wall comprising an ultrasonic emitter arranged to emit ultrasonic waves directed outwardly from a forward-to-rearward axis and a reflector having a plurality of active regions at least partially surrounding said axis, each said active region being arranged to focus ultrasonic waves into at least a portion of a loop-like focal region associated with that active region, each said focal region at least partially surrounding said axis, different focal regions associated with different ones of said active regions having different diameters.

59. Apparatus as claimed in claim 58 wherein said active regions are arranged so that a first one of said active regions lies forwardly of a second one of said active regions.

60. Apparatus as claimed in claim 58 wherein each of said active regions entirely encircles said axis.

61. Apparatus as claimed in claim 58 wherein each of said active regions is in the form of a full or partial surface of revolution about said axis, each such surface of revolution having a generatrix in the form of a portion of a parabola.

62. Apparatus as claimed in claim 58 wherein said emitter is adapted to direct ultrasonic waves selectively onto different ones of said active regions.

63. Apparatus as claimed in claim 58 wherein said reflector includes one or more balloons defining said active regions.

64. Apparatus for cardiac ablation comprising:

(a) an expansible reflector surrounding a forward-to-rearward axis; and

(b) an ultrasonic emitter adapted to direct ultrasonic waves generally outwardly from said axis and

rearwardly so that the ultrasonic waves impinge on the reflector and is reflected generally forwardly and outwardly from said axis.

65. Apparatus as claimed in claim 64 wherein said emitter includes a phased array.

66. Apparatus as claimed in claim 64 wherein said emitter has an exterior surface sloping outwardly from said axis in the forward direction.

67. Apparatus as claimed in claim 64 wherein said reflector includes an active region in the form of a surface of revolution about said axis, said surface of revolution having a generatrix in the form of a portion of a parabola.

68. Ultrasonic apparatus comprising:

(a) an ultrasonic emitter; and

(b) an inflatable structure defining one or more reflective surfaces defining a channel having an entry and an exit window, said ultrasonic emitter being adapted to direct ultrasonic waves into the entry of said channel, said one or more reflective surfaces being adapted to direct the ultrasonic waves through said channel from said entry to said exit window.

69. Apparatus as claimed in claim 68 wherein said channel narrows from said entry to said exit window.

70. Apparatus as claimed in claim 69 wherein said one or more reflective surfaces include first and second reflective surfaces converging with one another from said entry to said exit window.

71. Apparatus as claimed in claim 70 wherein said inflatable structure includes a first reflector balloon having a wall defining said first reflective surface and a second balloon having a wall defining said second reflective surface.

72. Apparatus as claimed in claim 71 wherein said inflatable structure further includes a structural balloon

having an exit wall extending across said exit window, from said first reflector balloon to said second reflector balloon.

73. Apparatus as claimed in claim 72 further comprising a source of a liquid connected to said structural balloon and one or more sources of a gas connected to said reflector balloons.

74. Apparatus as claimed in claim 71 wherein said first and second reflective surfaces are at least partial surfaces of revolution about a common axis and said exit window is in the form of a slot extending at least partially around said axis.

75. Apparatus as claimed in claim 74 wherein said second reflective surface includes a surface of revolution about said axis of a generatrix in the form of an exponential curve.

76. Apparatus as claimed in claim 68 further comprising a catheter having proximal and distal ends, said emitter and said inflatable structure being mounted to said catheter adjacent said distal end.

77. Ultrasonic apparatus comprising:

(a) a ultrasonic emitter having an emission surface in the form of at least a sector of a surface of revolution about an axis and adapted to direct ultrasonic waves generally radially outwardly away from said central axis; and

(b) a Fresnel lens at least partially encircling said emitter, said lens being constructed and arranged to deflect radially-directed ultrasonic waves axially along said central axis.

78. Apparatus as claimed in claim 77 wherein said Fresnel lens is arranged to direct at least a portion of said ultrasonic waves in a rearward direction along said axis, the apparatus further comprising a reflector disposed rearwardly of said lens and adapted to reflect rearwardly-directed ultrasonic waves from said lens forwardly and radially outwardly away from said axis.

79. Apparatus as claimed in claim 77 wherein said emitting surface is in the form of a complete surface of revolution about said axis and said Fresnel lens entirely encircles said emitter.

80. Apparatus as claimed in claim 79 wherein said emitting surface is cylindrical.

81. Apparatus as claimed in claim 79 wherein said Fresnel lens includes a helical element having a plurality of turns.

82. Apparatus as claimed in claim 81 wherein said turns are spaced axially from one another so as to define gaps between adjacent turns.